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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,887	03/05/2002	Benjamin Eithan Reubinoff	13164A	7135

7590 08/25/2004

Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, NY 11530

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/090,887

**Applicant(s)**

REUBINOFF ET AL.

**Examiner**

Joseph T. Voitach

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on October 2, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33,34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,34 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/436,164.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application filed March 5, 2002, is a divisional of 09/436,164, filed November 9, 1999, which claims benefit of foreign applications PP7009, filed November 9, 1998, and PQ2852, filed September 15, 1999, both filed in Australia.

Applicants' amendment filed March 5, 2002 has been received and entered. Claims 1-32 and 35 have been canceled. Claims 33, 34 and 36 are pending and currently under examination.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, starting on page 25 a list of references is provided, however not every reference has been listed in an IDS nor has a copy been provided. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-26, 38-44, 47-55 of copending Application No. 09/436,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because if the instantly claimed product is found allowable, methods of making and using the product supported by the specification would have to be considered. Claim 36 broadly encompasses any described embryonic stem cell, and in particular refers to a cell referenced in the examples. The examples provide a reduction to practice of culturing human embryonic stem cells and differentiating the cells in culture into defined lineages. Therefore, because the product is being examined any method of making and using would be considered obvious methodology.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. Specifically, claim 36 is rejected as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The claim appears to be drawn to a human embryonic stem cell line, however there is no description of human embryonic stem cell lines in any of the examples provided in the specification, only the propagation of isolated inner cell mass cells for several passages. In addition, "the examples" does not have antecedent basis and it is unclear if then it is reference to the examples of the specification, those of cited references or any of examples in the art.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipate by Thomson *et al.*

(Science 282:1145-1147-IDS Reference).

The claims recite a "human embryonic stem cell herein before described" and based on the methods disclosing the isolation of stem cells can reasonably interpreted as an embryonic cell isolated in the same or similar manner. Thomson *et al.* teach human pluripotent embryonic cell lines. Thomson *et al.* teach three cell lines: H13 and H14 which have a normal XY karyotype and H7 which has a normal XX karyotype (page 1145; second column). Thomson *et al.* teach

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that when the cell lines are injected into an immunodeficient mouse the cell lines can differentiate into endoderm, mesoderm and ectoderm cell types (page 1146; middle of first column and page 1147; figure 4). Further, characterization of the lines in culture, differentiation of the cells results in various cell types, including neuronal cells (neural epithelium shown in figure 4B). In characterizing the stem cell lines, various culturing methods were used to differentiate the cell lines. Among the parameters taught to affect differentiation of the cell lines was the feeder layer, the cell density, and various growth factors. In view of the breadth and lack of clarity of the claimed methodology the methods and general teachings of Thomson *et al.* describing methods to stimulate or allowing the cell lines to differentiate in culture, anticipate the methods set forth in the instant claims.

Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipate by Thomson (US Patent 6,200,806-IDS Reference).

Thomson teaches a purified preparation of pluripotent human embryonic stem cells which are capable of differentiating into derivatives of the endoderm, mesoderm and ectoderm. Again, in the characterization of the cells it is demonstrated that the cells can differentiate into neural cells (column 11; lines 31-32). Further, conditions to culture the cells in gelatin treated culture plates is taught when placed in culture and allowed to grow for two weeks after achieving confluence, or grown without a fibroblast feeder layer the cells spontaneously differentiate (description in paragraphs bridging columns 14-15 and in Figure 6). Thus, the differentiated human cells and methods to differentiate said cells from pluripotent embryonic cells taught in Thomson *et al.* anticipate the claims.

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Claims 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipate by Vajta *et al.* (Acta Vet Scan, 1997 or Mol Reprod Dev, 1998-IDS reference).

Claim 33 is drawn to a method of preserving a differentiated or undifferentiated cell, essentially any cell, by vitrification. Dependent claim 34 specifically indicates that the method is the Open Pulled Straw method of vitrification. The specification does not specifically define the Open Pulled Straw method, however references Vajta *et al.* (1998) (page 25, lines 2-4). Vajta *et al.* (1998) is a prior art reference that teaches the Open Pulled Straw method for the vitrification of ova and embryos which represent differentiated and undifferentiated cell types. Similarly, Vajta *et al.* (1997) is a prior art reference that teaches the Open Pulled Straw method for cryopreserving morula, blastocysts and embryos of the pig (see table I for example).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Reubinoff *et al.* Hum Reprod 16(10):2187-2194 (2001) is a post-filing refernece that the Open pulled Straw method for the vitrification of cells can be used to cryopreserving undifferentiated cells such as human embryonic cells. Further, it is noted that the specifi method used is that of Vajta *et al.* (1998a) (page 2188, Materials and Methods section)

### ***Conclusion***

No claim is allowed.

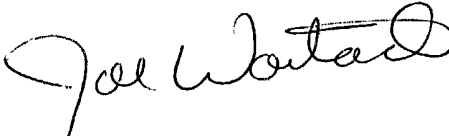
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

  
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